UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,008	12/20/2000	Marina Chuenkova	1322.1028-001	7228

21005 7590 10/18/2004

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/745,008	CHUENKOVA ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,27-33,42 and 44-53* is/are pending in the application.

4a) Of the above claim(s) *42 and 44-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *25,27-33,42 and 44-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-28-04 has been entered.

2. The amendment filed 3-24-04 has been entered into the record and has been fully considered.

3. Claims 26, 34-41, 43, and 54-58 are canceled. Claims 25, 27-33, 42 and 44-53 are pending.

Election/Restriction

4. Applicant's previous election with traverse of Group III, to the extent of SEQ ID NO:14 in a telephone inquiry with Robert Underwood (see Office Action of 5-19-03) is acknowledged.

The requirement is still deemed proper and is therefore maintained as FINAL (see 5-19-03 Office Action).

5. Claims 42 and 44-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5-19-03. The Examiner notes that claims 42 and 44-53 are no longer linked to the elected invention of SEQ ID NO:14.

Claim Rejections - 35 USC § 112

6. Claims 25 and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection. Applicants point to support for the new claim recitations within p. 24, lines 18-20 and at p. 22, lines 8-19. However, the Examiner fails to find support for the combination of elements that now define the claims. The recitations constitute new matter absent evidentiary support for the combination of recitations now recited which serve to delineate a new genus/sub-genus not apparently contemplated at the time of filing. To obtain the benefit of the priority document Applicant's should additionally note where such support may be found within the provisional application as the Examiner has been unable to find support for the combination of elements that now define the invention.

Priority

7. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119(e) as follows:The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of

35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The new matter rejection is noted above. Further, a claim may only be examined with respect to a single effective filing date. Accordingly benefit of priority to the previously filed applications cannot be established. Accordingly, the filing date awarded instant claims is that of the instant filing date, 8-4-04. Prior art is cited accordingly. Perfection of priority is dependent upon support for the claim recitations within instant and previously filed provisional '881.

Claim Rejections - 35 USC § 102 and 103

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 25, 27, 30 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by IDS reference AX, Pereira et al., J. Exp. Med., 174:179-91 as further evidenced by Stratagene, Product Info – pBlueScript® II Phagemid Vector obtained at "www.stratagene.com/products/displayProduct.aspx?pid=267" and associated map available from the ATCC as noted with Accession No. 87047 obtained at "www.atcc.org/SearchCatalogs/directdetail.cfm?collecion=mb-vector&atccNum=87047".

Pereira et al., teach trypanosoma cruzi Neuraminidase sequence corresponding with 100% identity to a peptide comprising SEQ ID NO:14, in particular SEQ ID NO:14 corresponds to residues 379-392 of the neruaminidase, see in particular Figure 3. Thus, the disclosure anticipates the limitations of claim 25 as directed to the element of an amino acid sequence that has (comprises) at least 90% amino acid sequence identity to SEQ ID NO:14. Pereira further teaches the neuraminidase trans-sialidase as a composition isolated from recombinant TCNA clones obtained from E coli XL-1 Blue transformed with pBluescript containing TCNA inserts. The bacteria were grown to an OD550=1.0, in PBS and lysed by freezing in liquid nitrogen in the presence of protease inhibitors 5 μM Pepstatin and leupeptin, 10mM EDTA, 5mM iodoacetaminde and 10 μg/ml soybean trypsin inhibitor, in PBS, see in particular Materials and Methods, pp. 180-181. Thus, the disclosure anticipates the limitations of claim 27 with physiologically

acceptable carrier. Claim 30 is directed to fusion proteins. Pereira teaches DNA sequencing and analysis of DNA inserts subcloned into Stratagene pBluescript vectors. As noted in the Stratagene pBluescript data sheet, screening is by prokaryotic expression with antibodies or nucleic acid probes and expression via such vectors is noted by expression of fusion proteins from the lac promoter. These are the screening and expression techniques noted via Pereira. As further noted via Pereira, Clone 7F insert was chosen for DNA sequencing because it consistently produced highest TCNA activity and a recombinant protein that reacted the strongest with TCN-1, TCN-2 and rabbit and mouse TCNA antibodies. Thus, Pereira teaches expression of TCNA fusion protein in the expression vector pBluescript as further evidenced by Stratagene, Product Info – pBlueScript® II Phagemid Vector and the associated map available from the ATCC as noted with Accession No. 87047 teaching the vector map, sequence and expression sites including LacUV5 P promoter (fusion partner). As noted above, the fusion protein is noted in growth culture and PBS in the presence of protease inhibitors for example. Thus, Pereira also teaches the limitations of claims 30 and 33 and therefore anticipates the claimed invention.

11. Claims 25 and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over IDS reference AX, Pereira et al., J. Exp. Med., 174:179-91, 1991 in view of IDS reference AU, Chuenkova et al., Mol. Biol. Of the Cell, 11:1487-98, April 2000.

Periera et al., teach as set forth above including TCNA recombinant fusion protein expression.

Periera et al., is further relied on to its teachings of the structure of the

transsialidase protein, the enzyme activity and to the different portions of the molecule as identified for example in Figure 5, including with cysteine rich regions, Type III module, long terminal repeat and GPI-anchor. Periera evidences that the N-terminal cysteine rich region is believed to possess the enzymatic activity, see in particular pp. 187 columns I-II, Cysteine rich domain.

Chuenkova teaches that the transsialidase peptide exhibits neurite outgrowth and rescues PC12 cells from apoptotic death caused by growth factor deprivation. Chuenkova further notes that the neuroprotective properties map to the C terminus of the catalytic domain and that CNTF and LIF mammalian neurotrophic factors potentiate the neuroprotective trans-sialidase activities. Chuenkova further teaches the use of truncated or modified constructs of the transialidase to confirm the functional regions of the molecule as disclosed for example in Materials and Methods, pp. 1488-1489. Such constructs were prepared in pET 23b (Novagen). As noted such expressed polypeptides contain a His T7 tag and may be detected via anti-His T7.Tag antibody, see Cloning and Expression of Recombinant Fragments of TS, p. 1488.

One of skill in the art would be motivated by Chuenkova to provide the neuroprotective properties in a composition in the presence of either CNTF or LIF as evidenced by the noted superior effects in Chuenkova, see in particular paragraph spanning pp. 1491-1492 and second paragraph pp. 1492 and discussion.

One of skill in the art would further be motivated to provide such elements via recombinant fusion protein production with elements TS, CNTF and/or LIF to provide for the superior effects of neuroprotection and for the benefit and ease of providing high

quantity and pure recombianant protein products as evidence in Pereira and Chuenkova and as well established in the art. One of skill in the art would have expected positive results either in culture or via recombinant expression given the high skill in the art of recombinant cloning techniques as evidence by Chuenkova and Pereira and the superior effects noted in neuroprotection when the elements are combined as further evidenced by Pereira and Chuenkova. Thus, the cumulative reference teachings render obvious the claimed invention.

Status of Claims

12. No claims are allowed.

Conclusion

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

SHARON L. TURNER, PH.D.
PATENT EXAMINER

Sharon L. Turner, Ph.D.
October 6, 2004